

Form PTO-1449
(REV. 8-83)

U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket:
2003080-0142
(SK-893-B-US)

In re Application No.
10/728,041

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Applicant: Danishefsky *et al.*

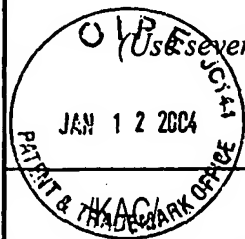
Filing Date:
December 3, 2003

Group: NYA

U. S. PATENT DOCUMENTS

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
/KAC/	* 5,053,489	Kufe <i>et al.</i>	10/1/91	530	350
	* 5,212,298	Rademacher <i>et al.</i>	5/18/93	536	55.2
	* 5,229,289	Kjeldsen <i>et al.</i>	7/20/93	435	240.27
	* 5,280,113	Rademacher <i>et al.</i>	1/18/94	536	55.2
	* 5,376,531	Anderson <i>et al.</i>	12/27/94	435	240.24
	* 5,421,733	Nudelman <i>et al.</i>	6/6/95	435	105
	* 5,491,088	Hellerstrom <i>et al.</i>	2/13/96	435	240.24
	* 5,625,030	Williams <i>et al.</i>	4/29/97	528	361
	* 5,660,834	Kjeldsen <i>et al.</i>	8/26/97	424	277.1
	* 5,679,769	Danishefsky	10/21/97	530	322
	* 5,683,674	Taylor-Papadimitriou <i>et al.</i>	11/4/97	424	1.49
	* 5,747,048	Kjeldsen <i>et al.</i>	5/5/98	424	277.1
	* 5,798,090	Longnecker <i>et al.</i>	8/25/98	424	279.1
	* 5,807,559	Jondal <i>et al.</i>	9/15/98	424	278.1
	* 5,858,994	Kretzschmar <i>et al.</i>	01/12/99	514	62
	* 5,871,990	Clausen <i>et al.</i>	2/16/99	435	193

INFORMATION DISCLOSURE STATEMENT

Applicant: Danishefsky *et al.*Filing Date:
December 3, 2003

Group: NYA

/KAC/	* 6,013,779	Wong <i>et al.</i>	1/11/00	536	18.6
/KAC/	6,090,789	Danishefsky <i>et al.</i>	7/18/00	514	25
/KAC/	* 6,222,020	Taylor-Papadimitriou <i>et al.</i>	4/24/01	530	395
/KAC/	* 6,238,668	Danishefsky <i>et al.</i>	5/29/01	424	184.1
/KAC/	US RE38,046 E	Longenecker <i>et al.</i>	3/25/03	424	279.1

U. S. PATENT APPLICATIONS

	Document No.	Applicant	Filing Date		
/KAC/	* USSN 08/457,485	Taylor-Papadimitriou <i>et al.</i>	6/1/95		

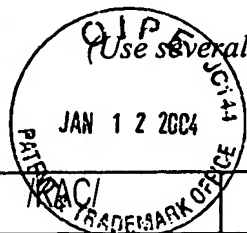
U. S. PATENT PUBLICATIONS

/KAC/	U.S. Publication No.	Applicant	Publication Date	Class	Subclass
/KAC/	US 2002/0006900	Danishefsky <i>et al.</i>	January 17, 2002	514	8
/KAC/	US 2002/0038017	Danishefsky <i>et al.</i>	March 28, 2002	536	53

FOREIGN PATENT DOCUMENTS

Examiner's Initials	Document No.	Country	Publication Date	Translation	
				Yes	No
/KAC/	* EP 341252	EP	11/19/97		
/KAC/	* JP 8-319300	JP	12/3/96		X

INFORMATION DISCLOSURE STATEMENT

Applicant: Danishefsky *et al.*Filing Date:
December 3, 2003

Group: NYA

/KAC/	* WO 96/34005	PCT	10/31/96		
/KAC/	* WO 96/40198	PCT	12/19/96		
/KAC/	* WO 98/30190	PCT	7/16/98		
/KAC/	* WO 98/46246	PCT	10/22/98		
/KAC/	WO 99/15201	PCT	4/1/99		
/KAC/	* WO 99/48515	PCT	9/30/99		
/KAC/	* WO 01/14395	PCT	03/01/01		

Examiner's
Initials

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, *Etc.*)

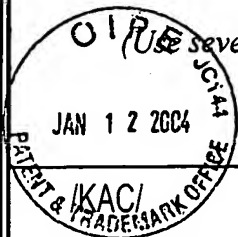
/KAC/	Allen <i>et al.</i> , "Pursuit of optimal carbohydrate-based anticancer vaccines: preparation of a multiantigenic unimolecular glycopeptide containing the Tn, MBr1, and Lewis ^y antigens", <i>J. Am. Chem. Soc.</i> , 123:1890-1897, 2001.
	* Allen, <i>et al.</i> , "A Second Generation Synthesis of the MBr1 (Globo-H) Breast Tumor Antigen: New Application of the N-Pentenyl Glycoside Method for Achieving Complex Carbohydrate Protein Linkages", <i>Chem. Eur. J.</i> , 6(8): 1366-1375, 2000.
	* Balcom, B.J. and Petersen, N.O., "Synthesis and Surfactant Behavior of an Unusual Cyclic Triester Based on a <i>cis</i> , <i>cis</i> -1, 3, 5-Cyclohexanetriol Headgroup," <i>Langmuir</i> , 7:2425-2427, 1991.
	* Bayle, <i>et al.</i> , "O-(3-Butenyl) A Stable Blocking Group Removable by Ozonolysis", <i>Carbohydrate Research</i> , 232: 375-380, 1992.
	* Bencomo <i>et al.</i> , "Synthesis of glycopeptides having clusters of O-glycosylic disaccharide chains. . .," <i>Carbohydrate Research</i> , 116, C9-C12, 1983.
	* Bilodeau M.T., "Total Synthesis of a Human Breast Tumro Associated Antigen", <i>J. Am. Chem. Soc.</i> , 117:7840-7841, 1995.
	Biswas <i>et al.</i> , "Construction of carbohydrate-based antitumor vaccines: synthesis of glycosyl amino acids by olefin cross-metathesis", <i>Tetrahedron Letters</i> , 43:6107-6110, 2002.
↓	Blackwell <i>et al.</i> , "New approaches to olefin cross-metathesis", <i>J. Am. Chem. Soc.</i> , 122:58-71, 2000.

INFORMATION DISCLOSURE STATEMENT

Applicant: Danishefsky *et al.*

Filing Date:
December 3, 2003

Group: NYA



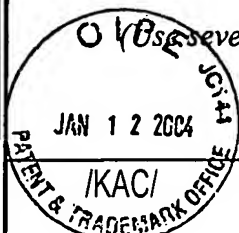
- * Boehm T. *et al.*, "Development of a Novel Silyl Ether Linker for Solid-Phase Organic Synthesis" *J. Org. Chem.*, 61:6498-6499, 1996.
- * Boon, T., "Toward a Genetic Analysis of Tumor Rejection Antigens," *Adv. Can. Res.*, 58:177-211, 1992.
- Bosse *et al.*, "Linear synthesis of the tumor-associated carbohydrate antigens Globo-H, SSEA-3, and Gb3", *J. Org. Chem.*, 67:6659-6670, 2002.
- * Broddefalk, *et al.*, "Preparation of a Glycopeptide Analogue of Type II Collagen - Use of Acid Labile Protective Groups for Carbohydrate Moieties in Solid Phase Synthesis of O-Linked Glycopeptides", *Tetrahedron Letters, NL, Elsevier Science*, 37(17): 3011-3014, 1996.
- * Cabaret, *et al.*, "Amphiphilic Liposaccharides. Synthesis and Reductive Cleavage of C-Allyl, O-Allyl, and O-Butenyl Glycosyl Derivatives", *Carbohydrate Research*, 189: 341-348, 1989.
- * Chan *et al.*, "Polymer-anchored Organosilyl Protecting Group in Organic Synthesis," *J. Chem. Soc., Chem. Commun.*, 909-911, 1985.
- * Collins and Ferrier "Monosaccharides: Their Chemistry and Their Roles in Natural Products, Publ. by John Wiley & Sons, Ltd., page 4, 1995.
- * Commissions on Nomenclature of Organic Chemistry and Physical Organic Chemistry, IUPAC, *Pure and Applied Chemistry*, 67, 1325 and 1334, 1995.
- * Danishefsky *et al.* "Glycals in Organic Synthesis: The Evolution of Comprehensive Strategies for the Assembly of Oligosaccharides and Glycoconjugates of Biological Consequence" *Angew. Chem. Int. Ed. Engl.*, 35:1380-1419, 1996.
- * Danishefsky *et al.* "From the Laboratory to the Clinic: A Retrospective on Fully Synthetic Carbohydrate-Based Anticancer Vaccines" *Angew. Chem. Int. Ed. Engl.*, 39:836-863, 2000.
- * Dermer, G.B., "Another Anniversary for the War on Cancer," *Bio/Technology*, 12, 320, 1994.
- * Deshpande *et al.*, "Strategy in Oligosaccharide Synthesis: An Application to a Concise Total Synthesis of the KH-1 (Adenocarcinoma) Antigen," *J. Am. Chem. Soc.*, 120, 1600-1614, 1998.
- * Elofsson and Kihlberg, "Synthesis of Tn and Sialyl Tn Building Blocks for Solid Phase Glycopeptide Synthesis," *Tetrahedron Letters*, 36, 7499-7502, 1995
- * Elofsson *et al.*, "Preparation of Tn and Sialyl Tn Building Blocks. . .," *Tetrahedron*, 53, 369-390, 1997.
- * Ezzell, "Cancer "Vaccines": An Idea Whose Time Has Come?" *J. NIH Res*, 7, 46-49, 1995.
- * Finn *et al.*, "MUC-1 Epithelial Tumor Mucin-based Immunity and Cancer Vaccines" *Immunol. Rev.*, 145, 61-89, 1995.
- * Freshney, R.I., "Culture of Animal Cells, A Manual of Basic Techniques, Alan R. Liss, Inc., New York, p. 3-4, 1983.
- * Fung *et al.*, "Active Specific Immunotherapy of Murine Mammary. . .," *Cancer Research*, 50, 4308-4314, 1990.

INFORMATION DISCLOSURE STATEMENT

Applicant: Danishefsky *et al.*

Filing Date:
December 3, 2003

Group: NYA



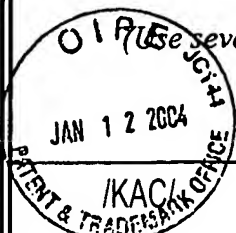
- Use several sheets if necessary*
- * Garg *et al.*, "Developments in the Synthesis of Glycopeptides Containing Glycosyl L-Asparagine, L-Serine, and L-Threonine" *Adv. Carb. Chem. Biochem.*, **50**, 277-310, 1994.
 - * Gleiter *et al.*, "Synthesis and Properties of Eight-and Ten-Membered Selenaradialenes," *Tetrahedron Letters*, **35**, 8779-8782, 1994.
 - * Grice *et al.*, "Tuning and Reactivity of Glycosides: Efficient One-pot Oligosaccharide Synthesis," *Synlett*, 781-784, 1995.
 - * Iijima, H. and Ogawa, T. "Synthesis of Mucin-type O-Glycosylated Amino Acid β -Gal-(1-3)-[α -Neu5Ac-2 6)]-GalNAc-(1 3)-Ser" *Carbohydr. Res.*, **186**, 95-106, 1989.
 - * Kaizu *et al.*, "Novel Fucolipids of Human Adenocarcinoma: Monoclonal Antibody Specific for Trifucosyl Le^Y (III³FucV³FucVI²FucnLc₆) and a Possible Three-dimensional Epitope Structure," *J. Biol. Chem.* **261**, 11254-11258, 1986.
 - * Kameyama *et al.*, "Total Synthesis of Sialyl Lewis X*," *Carbohydrate Research*, **209**, c1-c4, 1991.
 - Keding *et al.*, "Hydroxynorleucine as a glycosyl acceptor is an efficient means for introducing amino acid functionality into complex carbohydrates", *Tetrahedron Letters*, **44**:3413-3416, 2003.
 - * Kim *et al.*, "Expression of Le^Y and Extended Le^Y Blood Group-related Antigens in Human Malignant, Premalignant, and Nonmalignant Colonic Tissues," *Cancer Res.*, **46**, 5985-5992, 1986.
 - Kim *et al.*, "Effect of immunological adjuvant combinations on the antibody and T-cell response to vaccination with MUC1-KLH and GD3-KLH conjugates", *Vaccine*, **19**:530-537, 2001.
 - * Koganty *et al.*, "Glycopeptide- and Carbohydrate-based Synthetic Vaccines for the Immunotherapy of Cancer," *Drug Discovery Today*, **5**, 190-198, 1996.
 - * Kondo *et al.*, "In vitro Action of Human and Porcine α -amylases. . .," *Carbohydrate Research*, **204**, 207-213, 1990.
 - Kudryashov *et al.*, "Toward optimized carbohydrate-based anticancer vaccines: Epitope clustering, carrier structure, and adjuvant all influence antibody responses to lewis^Y conjugates in mice", *Proc. Natl. Acad. Sci. USA*, **98**:3264-3269, 2001.
 - * Kunz, H. and Birnbach, S., "Synthesis of O-Glycopeptides of the Tumor-Associated T_N. . .," *Angew. Chem. Int. Ed. Engl.*, **25**, 360-362, 1986.
 - * Lassaletta, *et al.*, "Glycosyl Imidates. Synthesis of the Hexasaccharide Moiety of Globo H (Human Breast Cancer) Antigen", *Liebigs Ann.* **9**: 1417-1423, 1996.
 - * Lay L. *et al.*, "Oligosaccharides Related to Tumor-Associated Antigens", *Helv. Chim. Acta*, **77**:509-514, 1994.
 - * Liebe, B. and Kunz, H., "Solid Phase Synthesis of a Tumor-Associated Sialyl-T_N Antigen Glycopeptide. . .," *Angew. Chem. Int. Ed. Engl.* **33**, 618-621, 1997.

INFORMATION DISCLOSURE STATEMENT

Applicant: Danishefsky *et al.*

Filing Date:
December 3, 2003

Group: NYA



* Lönn, H. "Synthesis of a Tri- and a Hepta-saccharide. . .," *Carbohydrate Research*, 139, 105-113, 1985

Nicolaou *et al.*, "A practical and enantioselective synthesis of glycosphingolipids and related compounds. Total synthesis of Globotriasosylceramide (Gb₃)", *J. Am. Chem. Soc.*, 110:7910-7912, 1988.

* Nicolaou *et al.*, "Stereocontrolled Synthesis of Sialyl Le^x. . .," *J. Chem. Soc., Chem. Commun.*, 870-872, 1991.

* Nudelman *et al.*, "Novel Fucolipids of Human Adenocarcinoma: Characterization of the Major Le^y Antigen of Human Adenocarcinoma as Trifucosylnonaosyl Le^y Lycolipid (III³FucV³FucVI²FucnLc₆), *J. Biol. Chem.*, 261, 11247-11253, 1986.

* Park, *et al.*, "Total Synthesis and Proof of Structure of a Human Breast Tumor (Globo-H) Antigen", *J. Am. Chem. Soc.*, 118(46): 11488-11500, 1996.

* Paulsen *et al.*, "Glycosidierung mit Thioglycosiden von Oligosacchariden zu Segmenten von O-Glycoproteinen" *Liebigs Ann. Chem.*, 75-86, 1988.

* Ragupathi *et al.*, "Immunization of Mice with a Fully Synthetic Globo H Antigen Results in Antibodies Against Human Cancer Cells: A Combined Chemical Immunological Approach to the Fashioning of an Anticancer Vaccine" *Angew. Chem. Int. Ed. Engl.* 36, 125-128, 1997.

* Ragupathi, *et al.*, "A Fully Synthetic Globo H Carbohydrate Vaccine Induces a Focused Humoral Response in Prostate Cancer Patients: A Proof of Principle", *Angew. Chem., Int. Ed.*, 38(4): 563-566, 1999.

* Ragupathi, G. "Carbohydrate Antigens as Targets for Active Specific Immunotherapy" *Cancer Immunol. Immunother.*, 43, 152-157, 1996.

Ragupathi *et al.*, "On the power of chemical synthesis: Immunological evaluation of models for multiantigenic carbohydrate-based cancer vaccines", *Proc. Natl. Acad. Sci. USA*, 99(21):13699-13704, 2002.

* Randolph J.T. *et al.*, "An Interactive Strategy for the Assembly of Complex, Branched Oligosaccharide Domains on a Solid Support: A Concise Synthesis of the Lewis^b Domain in Bioconjugatable Form", *Angew. Chem. Int. Ed/ Engl.*, 33(14):1470-1473, 1994.

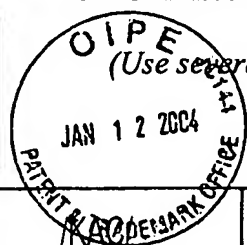
* Randolph *et al.*, "Major Simplifications in Oligosaccharide Syntheses Arising from a Solid-Phase Based Method: An Application to the Synthesis of the Lewis b Antigen," *J. Amer. Chem. Soc.*, 117, 5712-5719, 1995.

* Reid, *et al.*, "N-Pentenyl Glycosides in Organic Chemistry: A Contemporary Example of Serendipity", *Synlett*, 927-942, 1992.

* Roberge *et al.*, "A Strategy for a Convergent Synthesis of N-Linked Glycopeptides on a Solid Support," *Science* (Washington, D.C.), 269, 202-204, 1995.

* Schultheiss-Riemann, P. and Kunz, H., "O-Glycopeptide Synthesis. . .," *Angew. Chem. Int. Ed. Engl.*, 22, 62-63, 1983.

INFORMATION DISCLOSURE STATEMENT



Applicant: Danishefsky *et al.*

Filing Date:
December 3, 2003

Group: NYA

- * Seeberger *et al.*, "Synthesis of Biologically Important Oligosaccharides and Other Glycoconjugates by the Glycal Assembly Method," *Aldrichimica Acta*, **30**(3), 75-92, 1997.
- * Slovin *et al.*, "Carbohydrate Vaccines in Cancer: Immunogenicity of Fully Synthetic Globo H Hexasaccharide Conjugate in Man" *Proc. Natl. Acad. Sci. USA*, **96**, 5710-5715, 1999.
- * Spitler, "Cancer Vaccines: The Interferon Analogy," *Cancer Biotherapy*, **10**, 1-3, 1995.
- * Tao, M. and Levy, R. "Idiotypic/Granulocyte-macrophage Colony-simulating Factor Fusion Protein as a Vaccine for B-cell Lymphoma," *Nature*, **362**, 755-758, 1993.
- * Tokoyuni *et al.*, "Synthetic Vaccines: I. Synthesis of Multivalent Tn Antigen Cluster-Lysyllysine Conjugates," *Tetrahedron Lett.*, **31**, 2673-2676, 1990.
- * Tokoyuni, T. and Singhal, A.K., "Synthetic Carbohydrate. . .," *Chem. Soc. Rev.*, **24**, 231-242, 1995.
- * Toyokuni *et al.*, "Synthetic Carbohydrate Vaccines: Synthesis and Immunogenicity of Tn Antigen Conjugates", *Bioorg. Med. Chem.*, **2**, 1119-1132, 1994.
- * Udodong, *et al.*, "A Ready, Convergent Synthesis of the Heptasaccharide GPI Membrane Anchor of Rat Brain Thy-1 Glycoprotein" *J. Am. Chem. Soc.*, **115**: 7886-7887, 1993.
- * Waldmann *et al.* "New Enzymatic Protecting Group Techniques for the Construction of Peptides and Glycopeptides" *Biomed. Biochim. Acta*. **50** (10/11) S243-S248, 1991.
- Williams *et al.*, "In pursuit of an anticancer vaccine: a monomolecular construct containing multiple carbohydrate antigens", *Tetrahedron Letters*, **41**:9505-9508, 2000.
- * Yura *et al.*, "Preparation of oligosaccharide-linked polystyrene and method for immobilization of lectin and base materials for cells", abstract, Jpn. Kokai Tokkyo Koho (Japan), 03 December 1996.
- * Zhang *et al.*, "Immune Sera and Monoclonal Antibodies Define Two Configurations for the Sialyl Tn Tumor Antigen", *Cancer Res.*, **55**, 3364-3368, 1995.
- Database BIOSIS'Online! Biosciences Information Service, Philadelphia, PA, US; 22 March 2002, Kovbasnjuk Olga *et al.*, "Glycosphingolipid Gb3 as biomarker for invasive colon carcinoma cells", *FASEB Journal*, **16**(5):A1200, 2002, Annual Meeting of Professional Research Scientists on Experimental Biology; New Orleans, LA, USA, April 20-24, 2002.
- International Search Report issued for PCT application PCT/US03/22657

EXAMINER

/Karen A. Canella, Ph.D./

DATE CONSIDERED

07/09/2007

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

* denotes references cited in IDS'es submitted for parent applications USSN 09/083,776, filed March 25, 1998; and 10/209,618, filed July 31, 2002.

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark OfficeAttorney Docket
2003080-0142
(SK-893-B-US)In re Application
No.
10/728,041

(REV 1803)



INFORMATION

DISCLOSURE STATEMENT

(Use several sheets if necessary)

Applicant: Danishefsky *et al.*Filing Date:
December 3, 2003Group:
1642

U.S. PATENT DOCUMENTS

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Sub class

U.S. PATENT APPLICATIONS

Examiner's Initials:	Serial Number:	Applicant:	Filing Date:	Group:	Art Unit:

FOREIGN PATENT DOCUMENTS

Examiner's Initials	Document No.	Country	International Publication Date	Translation	
				Yes	No
/KAC/	WO 97/03995	WIPO	February 6, 1997		

OTHER DOCUMENTS

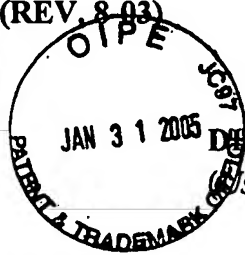
Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
/KAC/	Chen <i>et al.</i> , "Exploration of Modalities in Building a α -O-Linked Systems Through Glycal Assembly: A Total Synthesis of the Mucin-Related F1 α Antigen" <i>J. Am. Chem. Soc.</i> , 120 , 7760-7769, 1998.
/KAC/	Kudryashov <i>et al.</i> "Immunogenicity of Synthetic Conjugates of Lewis ^y Oligosaccharide with Proteins in Mice: Towards the Design of Anticancer Vaccines," <i>Cancer Immunol Immunother.</i> , 45 , 281-286, 1998.
/KAC/	Kuduk <i>et al.</i> "Synthetic and Immunological Studies on Clustered Modes of Mucin-Related Tn and TF O-Linked Antigens: The Preparation of a Glycopeptide-Based Vaccine for Clinical Trials against Prostate Cancer," <i>J. Am. Chem. Soc.</i> , 120 , 12474-12485, 1998.

Form PTO-1449
(REV. 8-03)

U.S. Department of Commerce
Patent and Trademark Office

Attorney Docket
2003080-0142
(SK-893-B-US)

In re Application
No.
10/728,041



INFORMATION

DISCLOSURE STATEMENT

(Use several sheets if necessary)

Applicant: Danishefsky *et al.*

Filing Date:
December 3, 2003

Group:
1642

/KAC/

Liu *et al.*, "Structurally Defined Synthetic Cancer Vaccines: Analysis of Structure, Glycosylation and Recognition of cancer Associated Mucin, MUC-1 Derived Peptides," *Glycoconjugate Journal*, 12, 607-617.

/KAC/

Paulsen *et al.*, "Synthesis of the Glycosyl Amino Acids.....," *Carbohydrate Research*, 268, 17-34, 1995

/KAC/

Qiu *et al.*, "Mucin Type Glycopeptides: Synthesis of Core 2, Core 6 and F1- α Building Blocks and Unexpected Reactions," *Tetrahedron Letters*, 38(1), 45-48, 1997.

/KAC/

Sames *et al.*, "Convergent Total Synthesis of a Tumor-Associated Mucin Motif," *Nature*, 389, 587-591, 1997.

/KAC/

Toyokuni *et al.*, "Synthetic Vaccines: Synthesis of a Dimeric Tn Antigen-Lipopeptide Conjugate that Elicits Immune Responses Against Tn-Expressing Glycoproteins," *J. Am. Chem. Soc.*, 116, 395-396, 1994.

/KAC/

Zhang, *et al.*, "Selection of Tumor Agents as Targets for Immune Attack Using Immunohistochemistry: II. Blood Group Related Antigens," *Int. J. Cancer*, 73, 50-56, 1997.

EXAMINER:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.